



Modular Program Report

The following report(s) provides findings from an FDA-initiated query using its Mini-Sentinel pilot. While Mini-Sentinel queries may be undertaken to assess potential medical product safety risks, they may also be initiated for various other reasons. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, exploring the feasibility of future, more detailed analyses within Mini-Sentinel, and seeking to better understand the capabilities of the Mini-Sentinel pilot.

Data obtained through Mini-Sentinel are intended to complement other types of evidence such as preclinical studies, clinical trials, postmarket studies, and adverse event reports, all of which are used by FDA to inform regulatory decisions regarding medical product safety. The information contained in this report is provided as part of FDA's commitment to place knowledge acquired from the Mini-Sentinel pilot in the public domain as soon as possible. Any public health actions taken by FDA regarding products involved in Mini-Sentinel queries will continue to be communicated through existing channels.

FDA wants to emphasize that the fact that FDA has initiated a query involving a medical product and is reporting findings related to that query does not mean that FDA is suggesting health care practitioners should change their prescribing practices for the medical product or that patients taking the medical product should stop using it. Patients who have questions about the use of an identified medical product should contact their health care practitioners.

The following report contains a description of the request, request specifications, and results from the modular program run(s).

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Overview

Request Description In June of 2013, FDA requested de novo programming to assess serious hypoglycemic events following use of anti-diabetic agents (ADAs). The request ID was MSY4_AH4. The program was based on Modular Program #3 (v6.0). The exposure and inclusion/exclusion portions of the program are original MP3 programming. The event portion of the program consists of de novo programming to classify events into two types of hypoglycemic events based on a validated algorithm. The modified MP3 outputs a few additional metrics for each of the two types of hypoglycemic events: event classification (NumEvents1, NumEvents2) and time-to-event/days at risk (DaysAtRisk1, DaysAtRisk2). Please see "*Hypoglycemia_DeNovo_Final_Specifications_ah4_08132013.pdf*" for more information.

This report provides results for a new request that makes use of the de novo programming completed for MSY4_AH4. The request is similar in that it examines hypoglycemic events (defined using the same algorithm as in MSY4_AH4) following use of ADAs. However, the ADAs are grouped in slightly different ways. Please see the Specifications tab for a list of scenarios examined in this request. The query was run against the Mini-Sentinel Distributed Database (MSDD) for the time period of January 1, 2004 - December 31, 2012. The request was distributed to 18 Data Partners in November 2013. This report includes results for scenarios 18-30 shown in the Specifications tab. These scenarios have a pre-existing dispensing requirement and use different incidence criteria than scenarios 1-17. Results for scenarios 1-17 are presented in a separate report (MSY5_MPR07_V1_Report1).

Request ID MSY5_MPR07_v1 Report 2 of 2

Specifications Program parameter inputs and scenarios

Glossary List of terms found in this report and their definitions

Table 1 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product

Table 2 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

Table 3 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

Table 4 Table of Summary of Incident ADA Use and Hypoglycemia in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

Notes: Please contact the Mini-Sentinel Operations Center (MSOC_Requests@harvardpilgrim.org) for questions and to provide comments/suggestions for future enhancements to this document.

Specifications for MSY5_MPR07_v1 - Hypoglycemia and ADAs

This report provides results for a new request that makes use of the de novo programming completed for MSY4_AH4. The request is similar in that it examines hypoglycemic events (defined using the same algorithm as in MSY4_AH4) following use of ADAs. However, the ADAs are grouped in slightly different ways. Please refer to Hypoglycemia_DeNovo_Final_Specifications_ah4_08132013.pdf for event algorithm and additional information. This report displays results for Scenarios 18-30. Please see MS_Brief_Report_MSYS_MPR07_v1_part1 for results on Scenarios 1-17.

Query dates: January 1, 2004 - December 31, 2012
Age Stratifications: 00-34 35-49 50-64 65-79 80+ Medical
Coverage Requirement: and Drug 45 Days
Enrollment Gap:

Drug/Exposure

Scenario	Incident exposure	Incident w/ respect to:	Washout (days)	Incidence Type	Episode Gap	Exposure Extension Period	Minimum Days Supplied
1	Chlorpropamide	All ADAs	183	SING	10	10	1
2	Glimepiride	All ADAs	183	SING	10	10	1
3	Glipizide	All ADAs	183	SING	10	10	1
4	Glipizide/Metformin	All ADAs	183	SING	10	10	1
5	Glyburide	All ADAs	183	SING	10	10	1
6	Glyburide/Metformin	All ADAs	183	SING	10	10	1
7	Tolazamide	All ADAs	183	SING	10	10	1
8	Pioglitazone	All ADAs	183	SING	10	10	1
9	Pioglitazone/Metformin	All ADAs	183	SING	10	10	1
10	Rosiglitazone Maleate	All ADAs	183	SING	10	10	1
11	Rosiglitazone/Metformin	All ADAs	183	SING	10	10	1
12	Insulin (Rapid-Acting)	All ADAs	183	SING	10	10	1
13	Insulin (Short-Acting)	All ADAs	183	SING	10	10	1
14	Insulin (Long-Acting)	All ADAs	183	SING	10	10	1
15	Insulin (Intermediate-Acting)	All ADAs	183	SING	10	10	1
16	Insulin (Intermediate/Rapid-Acting)	All ADAs	183	SING	10	10	1
17	Insulin (Intermediate/Short-Acting)	All ADAs	183	SING	10	10	1
18	Chlorpropamide	All ADAs except Metformin	183	SING	10	10	1
19	Glimepiride	All ADAs except Metformin	183	SING	10	10	1
20	Glipizide/Glipizide-Metformin	All ADAs except Metformin	183	SING	10	10	1
21	Glyburide/Glyburide-Metformin	All ADAs except Metformin	183	SING	10	10	1
22	Tolazamide	All ADAs except Metformin	183	SING	10	10	1
23	Pioglitazone/Pioglitazone-Metformin	All ADAs except Metformin	183	SING	10	10	1
24	Rosiglitazone Maleate/Rosiglitazone-Metformin	All ADAs except Metformin	183	SING	10	10	1
25	Insulin (Rapid-Acting)	All ADAs except Metformin	183	SING	10	10	1
26	Insulin (Short-Acting)	All ADAs except Metformin	183	SING	10	10	1
27	Insulin (Long-Acting)	All ADAs except Metformin	183	SING	10	10	1
28	Insulin (Intermediate-Acting)	All ADAs except Metformin	183	SING	10	10	1
29	Insulin (Intermediate/Rapid-Acting)	All ADAs except Metformin	183	SING	10	10	1
30	Insulin (Intermediate/Short-Acting)	All ADAs except Metformin	183	SING	10	10	1

*Requires de novo programming. See event algorithm.

** Program will consider only the first incident episode. All subsequent episodes will be excluded from the analysis.

NDC codes checked against First Data Bank's "National Drug Data File (NDDF) Plus"

ICD-9-CM diagnosis and procedure codes checked against "Ingenix 2012 ICD-9-CM Data File" provided by OptumInsight

HCPCS codes checked against "Optum 2012 HCPCS Level II Data File" provided by OptumInsight

CPT codes checked against "Optum 2012 Current Procedure Codes & Relative Values Data File" provided by OptumInsight

Glossary of Terms in Modular Program 3*

Blackout Period - number of days at the beginning of a treatment episode that events are to be ignored. If an event occurs during the blackout period, the episode is excluded.

Care Setting - type of medical encounter or facility where the exposure, event, or condition code was recorded. Possible care settings include: Inpatient Hospital Stay (IP), Non-Acute Institutional Stay (IS), Emergency Department (ED), Ambulatory Visit (AV), and Other Ambulatory Visit (OA).

Days at Risk - number of days supplied plus any episode gaps and exposure extension periods.

Eligible Members - Number of members eligible for an incident treatment episode (defined by the drug/exposure and event washout periods) with drug and medical coverage during the query period.

Enrollment Gap - number of days allowed between two consecutive enrollment periods without breaking a “continuously enrolled” sequence.

Episode Gap - number of days allowed between two (or more) consecutive exposures (dispensings/procedures) to be considered the same treatment episode.

Exposure Extension Period - number of days post treatment period in which the outcomes/events are counted for a treatment episode.

Incidence Type (drug/exposure)- *Minimum incidence type* will consider the first treatment episode in the query period as long as it is the first treatment episode in the user's entire available history. *Single* and *Multiple incidence types* will use the washout period to establish incidence, however *Single* will only consider the first treatment episode whereas *Multiple* will consider all qualifying incident treatment episodes.

Incidence Type (event/outcome)- *Minimum incidence type* considers the first event in a valid episode as long as it is the first event in the user's entire available history. *Multiple incidence type* uses the washout period to establish incidence and considers all qualifying incident treatment episodes. The program will only consider one event per episode, but the *Multiple incidence type* will consider more than one event per user if a user has more than one incident episode.

Lookback Period (pre-existing condition) - number of days wherein a member is required to have evidence of pre-existing condition (diagnosis/procedure/drug dispensing).

Member-Days - sum of all days of enrollment with medical and drug coverage** in the query period preceded by an exposure washout period.

Minimum Days Supplied - specifies a minimum number of days in length of the days supplied for the episode to be considered

Minimum Episode Duration - specifies a minimum number of days in length of the episode for it to be considered

New Episodes - new treatment episodes; length of episode is determined by days supplied in one dispensing (or consecutive dispensings bridged by the episode gap).

New Users - number of members with incident exposure during the query period. Member must have no evidence of exposure (s) of interest (defined by incidence criteria) in the prior washout period. A user may only be counted once in a query period.

Principal Diagnosis - diagnosis or condition established to be chiefly responsible for admission of the patient to the hospital. YES will only consider diagnoses flagged as Principal

Query Period - period in which the modular program looks for exposures and outcomes of interest.

Time to Event - time in days between treatment initiation and event.

Total Days Supplied - number of days supplied for all dispensings in qualifying treatment episodes.

Washout Period (drug/exposure)** - number of days a user is required to have no evidence of prior exposure (drug dispensing/procedure) and continuous drug and medical coverage prior to an incident treatment episode.

Washout Period (event/outcome)** - number of days a user is required to have no evidence of a prior event (procedure/diagnosis) and continuous drug and medical coverage prior to an incident treatment episode.

Years at Risk - number of days supplied plus any episode gaps and exposure extension periods all divided by 365.25.

*all terms may not be used in this report

**incident treatment episodes must be incident to both the exposure and the event

**Table 1: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012,
by ADA Product**

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Insulin (Rapid-Acting)	22,898	22,898	32,418	1,082,787	1,161,521	3,180	134	35	99	1,012
Insulin (Short-Acting)	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)	35,210	35,210	56,778	2,146,469	2,250,720	6,162	142	29	113	1,581
Insulin (Intermediate-Acting)	14,043	14,043	27,895	1,099,502	1,140,456	3,122	81	22	59	840
Insulin (Intermediate/Rapid-Acting)	2,886	2,886	6,377	255,814	266,440	729	29	8	21	2,740
Insulin (Intermediate/Short-Acting)	0	0	0	0	0	0	0	0	0	0
Chlorpropamide	48	48	125	5,980	6,207	17	1	0	1	0
Glimepiride	70,003	70,003	292,582	11,734,488	11,951,807	32,722	259	71	188	11,005
Glipizide/Glipizide-Metformin	163,021	163,021	670,171	37,384,876	37,186,859	101,812	1,281	302	979	87,247
Glyburide/Glyburide-Metformin	76,593	76,593	294,493	13,467,643	13,680,197	37,454	476	134	342	20,193
Tolazamide	3,639	3,639	9,683	868,204	849,998	2,327	27	18	9	8,286
Pioglitazone/Pioglitazone-Metformin	55,531	55,531	231,523	9,448,729	9,661,127	26,451	79	14	65	1,142
Rosiglitazone/Rosiglitazone-Metformin	13,299	13,299	54,110	1,921,776	1,981,447	5,425	23	7	16	344

Table 1: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)	4,587	2,247,452	1,020,673,195	10.2	47.3	1.4	33.4	11.5	42.1
Insulin (Short-Acting)	0	2,245,781	1,022,262,272	0.0	---	---	---	---	---
Insulin (Long-Acting)	5,292	2,248,088	1,021,161,759	15.7	61.0	1.6	37.8	6.3	23.0
Insulin (Intermediate-Acting)	2,468	2,246,724	1,021,244,841	6.3	78.3	2.0	39.4	7.1	25.9
Insulin (Intermediate/Rapid-Acting)	4,707	2,245,995	1,022,121,777	1.3	88.6	2.2	40.1	10.9	39.8
Insulin (Intermediate/Short-Acting)	0	2,245,781	1,022,262,272	0.0	---	---	---	---	---
Chlorpropamide	66	2,245,784	1,022,255,992	0.0	124.6	2.6	47.8	16.1	58.8
Glimepiride	23,222	2,247,337	1,019,485,839	31.1	167.6	4.2	40.1	2.2	7.9
Glipizide/Glipizide-Metformin	347,188	2,248,717	1,012,738,198	72.5	229.3	4.1	55.8	3.4	12.6
Glyburide/Glyburide-Metformin	51,023	2,248,162	1,016,991,061	34.1	175.8	3.8	45.7	3.5	12.7
Tolazamide	5,968	2,246,248	1,021,897,747	1.6	238.6	2.7	89.7	3.2	11.6
Pioglitazone/Pioglitazone-Metformin	16,556	2,249,726	1,018,487,446	24.7	170.2	4.2	40.8	0.8	3.0
Rosiglitazone/Rosiglitazone-Metformin	822	2,246,945	1,020,965,528	5.9	144.5	4.1	35.5	1.2	4.2

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2
Insulin (Rapid-Acting)									
00 to 34	2,777	2,777	4,235	139,746	146,032	400	23	7	16
35 to 49	5,474	5,474	7,816	256,342	271,349	743	26	5	21
50 to 64	8,008	8,008	11,482	402,247	428,984	1,174	40	13	27
65 to 79	4,847	4,847	6,666	228,279	249,341	683	30	5	25
80+	1,792	1,792	2,219	56,173	65,815	180	15	5	10
Insulin (Short-Acting)									
00 to 34	0	0	0	0	0	0	0	0	0
35 to 49	0	0	0	0	0	0	0	0	0
50 to 64	0	0	0	0	0	0	0	0	0
65 to 79	0	0	0	0	0	0	0	0	0
80+	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)									
00 to 34	2,834	2,834	4,082	135,872	143,556	393	17	4	13
35 to 49	9,496	9,496	14,740	509,390	544,144	1,490	29	4	25
50 to 64	14,647	14,647	24,345	915,159	957,199	2,621	47	9	38
65 to 79	6,948	6,948	11,543	502,674	520,155	1,424	34	8	26
80+	1,285	1,285	2,068	83,374	85,666	235	15	4	11
Insulin (Intermediate-Acting)									
00 to 34	2,345	2,345	3,807	132,776	135,973	372	12	3	9
35 to 49	3,769	3,769	7,001	258,103	267,812	733	13	0	13
50 to 64	4,830	4,830	10,876	451,687	469,757	1,286	18	7	11
65 to 79	2,654	2,654	5,433	224,687	232,797	637	31	9	22
80+	445	445	778	32,249	34,117	93	7	3	4
Insulin (Intermediate/Rapid-Acting)									
00 to 34	188	188	412	13,460	14,207	39	3	0	3
35 to 49	629	629	1,239	45,946	49,295	135	1	0	1
50 to 64	1,100	1,100	2,534	104,698	108,532	297	14	5	9
65 to 79	803	803	1,823	78,161	79,951	219	10	3	7
80+	166	166	369	13,549	14,455	40	1	0	1

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 1	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)										
00 to 34	114	520	305,402	92,656,239	9.1	50.3	1.5	33.0	15.7	57.5
35 to 49	160	308	608,128	215,644,493	9.0	46.8	1.4	32.8	9.6	35.0
50 to 64	467	2,533	938,183	411,273,631	8.5	50.2	1.4	35.0	9.3	34.1
65 to 79	217	600	484,845	253,539,621	10.0	47.1	1.4	34.2	12.0	43.9
80+	54	626	90,385	47,559,211	19.8	31.3	1.2	25.3	22.8	83.2
Insulin (Short-Acting)										
00 to 34	0	0	305,257	92,776,661	0.0	---	---	---	---	---
35 to 49	0	0	607,979	216,021,901	0.0	---	---	---	---	---
50 to 64	0	0	937,727	411,749,163	0.0	---	---	---	---	---
65 to 79	0	0	484,584	253,968,029	0.0	---	---	---	---	---
80+	0	0	90,427	47,746,518	0.0	---	---	---	---	---
Insulin (Long-Acting)										
00 to 34	97	185	305,345	92,697,821	9.3	47.9	1.4	33.3	11.8	43.3
35 to 49	140	1,274	608,321	215,748,144	15.6	53.6	1.6	34.6	5.3	19.5
50 to 64	157	2,182	938,438	411,322,723	15.6	62.5	1.7	37.6	4.9	17.9
65 to 79	1,015	871	485,136	253,717,489	14.3	72.3	1.7	43.5	6.5	23.9
80+	172	780	90,465	47,675,582	14.2	64.9	1.6	40.3	17.5	64.0
Insulin (Intermediate-Acting)										
00 to 34	119	412	305,358	92,623,065	7.7	56.6	1.6	34.9	8.8	32.2
35 to 49	0	467	607,898	215,625,689	6.2	68.5	1.9	36.9	4.9	17.7
50 to 64	279	371	937,952	411,509,629	5.1	93.5	2.3	41.5	3.8	14.0
65 to 79	398	1,016	484,728	253,788,195	5.5	84.7	2.0	41.4	13.3	48.6
80+	44	202	90,408	47,698,263	4.9	72.5	1.7	41.5	20.5	74.9
Insulin (Intermediate/Rapid-Acting)										
00 to 34	0	70	305,265	92,768,388	0.6	71.6	2.2	32.7	21.1	77.1
35 to 49	0	248	608,003	215,995,715	1.0	73.0	2.0	37.1	2.0	7.4
50 to 64	1,402	2,645	937,782	411,692,140	1.2	95.2	2.3	41.3	12.9	47.1
65 to 79	1,338	1,718	484,627	253,931,295	1.7	97.3	2.3	42.9	12.5	45.7
80+	0	26	90,425	47,734,239	1.8	81.6	2.2	36.7	6.9	25.3

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2
Insulin (Intermediate/Short-Acting)									
00 to 34	0	0	0	0	0	0	0	0	0
35 to 49	0	0	0	0	0	0	0	0	0
50 to 64	0	0	0	0	0	0	0	0	0
65 to 79	0	0	0	0	0	0	0	0	0
80+	0	0	0	0	0	0	0	0	0
Chlorpropamide									
00 to 34	0	0	0	0	0	0	0	0	0
35 to 49	12	12	30	900	916	3	0	0	0
50 to 64	10	10	12	620	714	2	0	0	0
65 to 79	23	23	80	4,310	4,397	12	1	0	1
80+	3	3	3	150	180	0	0	0	0
Glimepiride									
00 to 34	2,422	2,422	6,779	221,465	235,525	645	5	3	2
35 to 49	15,768	15,768	55,437	1,930,336	2,015,154	5,517	28	4	24
50 to 64	30,562	30,562	130,985	5,022,904	5,116,696	14,009	87	30	57
65 to 79	18,186	18,186	84,253	3,905,843	3,927,733	10,754	89	23	66
80+	3,065	3,065	15,128	653,940	656,699	1,798	50	11	39
Glipizide/Glipizide-Metformin									
00 to 34	5,895	5,895	15,254	759,042	763,241	2,090	30	6	24
35 to 49	38,728	38,728	131,778	6,786,878	6,836,758	18,718	198	38	160
50 to 64	71,937	71,937	302,760	16,833,028	16,744,658	45,844	421	87	334
65 to 79	39,158	39,158	184,974	11,059,279	10,926,200	29,914	468	121	347
80+	7,303	7,303	35,405	1,946,649	1,916,002	5,246	164	50	114

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 1	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Insulin (Intermediate/Short-Acting)										
00 to 34	0	0	305,257	92,776,661	0.0	---	---	---	---	---
35 to 49	0	0	607,979	216,021,901	0.0	---	---	---	---	---
50 to 64	0	0	937,727	411,749,163	0.0	---	---	---	---	---
65 to 79	0	0	484,584	253,968,029	0.0	---	---	---	---	---
80+	0	0	90,427	47,746,518	0.0	---	---	---	---	---
Chlorpropamide										
00 to 34	0	0	305,257	92,776,661	0.0	---	---	---	---	---
35 to 49	0	0	607,979	216,020,197	0.0	75.0	2.5	30.0	0.0	0.0
50 to 64	0	0	937,728	411,748,088	0.0	62.0	1.2	51.7	0.0	0.0
65 to 79	0	66	484,584	253,965,079	0.0	187.4	3.5	53.9	22.7	83.1
80+	0	0	90,427	47,745,967	0.0	50.0	1.0	50.0	0.0	0.0
Glimepiride										
00 to 34	85	49	305,281	92,705,088	7.9	91.4	2.8	32.7	2.1	7.8
35 to 49	621	1,726	608,093	215,498,816	25.9	122.4	3.5	34.8	1.4	5.1
50 to 64	5,517	5,513	937,843	410,584,322	32.6	164.4	4.3	38.3	1.7	6.2
65 to 79	3,249	9,927	484,737	253,140,188	37.5	214.8	4.6	46.4	2.3	8.3
80+	1,533	6,007	90,291	47,557,425	33.9	213.4	4.9	43.2	7.6	27.8
Glipizide/Glipizide-Metformin										
00 to 34	739	2,351	305,293	92,596,248	19.3	128.8	2.6	49.8	3.9	14.4
35 to 49	6,165	35,443	607,858	214,265,749	63.7	175.2	3.4	51.5	2.9	10.6
50 to 64	26,426	135,001	936,919	407,583,354	76.8	234.0	4.2	55.6	2.5	9.2
65 to 79	42,367	138,018	484,006	251,139,106	80.9	282.4	4.7	59.8	4.3	15.6
80+	11,550	36,375	89,994	47,153,741	81.1	266.6	4.8	55.0	8.6	31.3

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2
Glyburide/Glyburide-Metformin									
00 to 34	4,598	4,598	11,516	436,670	456,725	1,250	22	6	16
35 to 49	19,592	19,592	65,047	2,817,067	2,901,816	7,945	66	16	50
50 to 64	32,302	32,302	131,308	5,994,518	6,083,658	16,656	156	44	112
65 to 79	16,889	16,889	72,603	3,580,782	3,600,278	9,857	161	49	112
80+	3,212	3,212	14,019	638,606	637,720	1,746	71	19	52
Tolazamide									
00 to 34	130	130	297	25,142	24,328	67	2	1	1
35 to 49	856	856	2,125	188,059	183,800	503	2	2	0
50 to 64	1,563	1,563	4,362	392,098	384,313	1,052	9	4	5
65 to 79	919	919	2,453	225,357	221,440	606	11	8	3
80+	171	171	446	37,548	36,117	99	3	3	0
Pioglitazone/Pioglitazone-Metformin									
00 to 34	2,991	2,991	8,319	280,775	300,008	821	8	1	7
35 to 49	14,769	14,769	54,389	2,052,833	2,127,052	5,824	21	4	17
50 to 64	25,506	25,506	116,361	4,749,364	4,832,463	13,231	29	8	21
65 to 79	10,792	10,792	46,280	2,107,820	2,139,041	5,856	20	1	19
80+	1,473	1,473	6,174	257,937	262,563	719	1	0	1
Rosiglitazone/Rosiglitazone-Metformin									
00 to 34	1,089	1,089	3,120	101,174	107,372	294	3	2	1
35 to 49	3,756	3,756	13,859	464,849	484,655	1,327	5	1	4
50 to 64	6,035	6,035	26,884	974,603	999,427	2,736	7	4	3
65 to 79	2,153	2,153	9,236	345,811	353,327	967	7	0	7
80+	266	266	1,011	35,339	36,666	100	1	0	1

Table 2: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Age Group

	Time to Event Group 1	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Glyburide/Glyburide-Metformin										
00 to 34	124	580	305,308	92,553,941	15.1	95.0	2.5	37.9	4.8	17.6
35 to 49	1,196	5,180	607,908	214,897,341	32.2	143.8	3.3	43.3	2.3	8.3
50 to 64	9,061	21,803	937,604	409,571,075	34.5	185.6	4.1	45.7	2.6	9.4
65 to 79	7,711	16,818	484,632	252,575,554	34.8	212.0	4.3	49.3	4.5	16.3
80+	2,101	6,642	90,228	47,393,150	35.6	198.8	4.4	45.6	11.1	40.7
Tolazamide										
00 to 34	2,412	252	305,258	92,769,968	0.4	193.4	2.3	84.7	8.2	30.0
35 to 49	1,204	0	607,993	215,952,248	1.4	219.7	2.5	88.5	1.1	4.0
50 to 64	807	3,401	937,823	411,599,092	1.7	250.9	2.8	89.9	2.3	8.6
65 to 79	2,879	2,315	484,647	253,860,909	1.9	245.2	2.7	91.9	5.0	18.1
80+	984	0	90,442	47,715,530	1.9	219.6	2.6	84.2	8.3	30.3
Pioglitazone/Pioglitazone-Metformin										
00 to 34	37	158	305,305	92,592,375	9.8	93.9	2.8	33.8	2.7	9.7
35 to 49	498	2,628	608,264	215,252,610	24.3	139.0	3.7	37.7	1.0	3.6
50 to 64	411	7,249	938,648	410,149,608	27.2	186.2	4.6	40.8	0.6	2.2
65 to 79	196	6,434	485,379	252,913,421	22.2	195.3	4.3	45.5	0.9	3.4
80+	0	87	90,431	47,579,432	16.3	175.1	4.2	41.8	0.4	1.4
Rosiglitazone/Rosiglitazone-Metformin										
00 to 34	21	149	305,278	92,672,322	3.6	92.9	2.9	32.4	2.8	10.2
35 to 49	35	166	608,024	215,710,831	6.2	123.8	3.7	33.5	1.0	3.8
50 to 64	288	26	937,996	411,206,508	6.4	161.5	4.5	36.3	0.7	2.6
65 to 79	0	417	484,745	253,675,935	4.4	160.6	4.3	37.4	2.0	7.2
80+	0	64	90,428	47,699,932	2.9	132.9	3.8	35.0	2.7	10.0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Insulin (Rapid-Acting)										
Female	13,099	13,099	18,643	614,441	660,187	1,807	64	17	47	399
Male	9,799	9,799	13,775	468,346	501,334	1,373	70	18	52	613
Unknown	0	0	0	0	0	0	0	0	0	0
Insulin (Short-Acting)										
Female	0	0	0	0	0	0	0	0	0	0
Male	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Insulin (Long-Acting)										
Female	17,259	17,259	27,710	1,038,815	1,090,363	2,985	70	12	58	398
Male	17,950	17,950	29,067	1,107,626	1,160,319	3,177	72	17	55	1,183
Unknown	1	1	1	28	38	0	0	0	0	0
Insulin (Intermediate-Acting)										
Female	8,653	8,653	16,637	650,736	674,723	1,847	39	11	28	385
Male	5,389	5,389	11,257	448,676	465,633	1,275	42	11	31	455
Unknown	1	1	1	90	100	0	0	0	0	0
Insulin (Intermediate/Rapid-Acting)										
Female	1,556	1,556	3,273	124,613	132,366	362	13	4	9	1,367
Male	1,330	1,330	3,104	131,201	134,074	367	16	4	12	1,373
Unknown	0	0	0	0	0	0	0	0	0	0
Insulin (Intermediate/Short-Acting)										
Female	0	0	0	0	0	0	0	0	0	0
Male	0	0	0	0	0	0	0	0	0	0
Unknown	0	0	0	0	0	0	0	0	0	0
Chlorpropamide										
Female	14	14	28	1,550	1,653	5	0	0	0	0
Male	34	34	97	4,430	4,554	12	1	0	1	0
Unknown	0	0	0	0	0	0	0	0	0	0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)									
Female	2,901	1,254,511	566,173,808	10.4	46.9	1.4	33.0	9.7	35.4
Male	1,686	992,865	454,471,459	9.9	47.8	1.4	34.0	14.0	51.0
Unknown	0	76	27,928	0.0	---	---	---	---	---
Insulin (Short-Acting)									
Female	0	1,253,568	567,199,249	0.0	---	---	---	---	---
Male	0	992,137	455,035,095	0.0	---	---	---	---	---
Unknown	0	76	27,928	0.0	---	---	---	---	---
Insulin (Long-Acting)									
Female	2,294	1,254,735	566,663,821	13.8	60.2	1.6	37.5	6.4	23.4
Male	2,998	993,277	454,469,986	18.1	61.7	1.6	38.1	6.2	22.7
Unknown	0	76	27,952	13.2	28.0	1.0	28.0	0.0	0.0
Insulin (Intermediate-Acting)									
Female	1,797	1,254,160	566,468,359	6.9	75.2	1.9	39.1	5.8	21.1
Male	671	992,488	454,748,554	5.4	83.3	2.1	39.9	9.0	32.9
Unknown	0	76	27,928	13.2	90.0	1.0	90.0	0.0	0.0
Insulin (Intermediate/Rapid-Acting)									
Female	1,596	1,253,675	567,114,857	1.2	80.1	2.1	38.1	9.8	35.9
Male	3,111	992,244	454,978,992	1.3	98.6	2.3	42.3	11.9	43.6
Unknown	0	76	27,928	0.0	---	---	---	---	---
Insulin (Intermediate/Short-Acting)									
Female	0	1,253,568	567,199,249	0.0	---	---	---	---	---
Male	0	992,137	455,035,095	0.0	---	---	---	---	---
Unknown	0	76	27,928	0.0	---	---	---	---	---
Chlorpropamide									
Female	0	1,253,569	567,196,034	0.0	110.7	2.0	55.4	0.0	0.0
Male	66	992,139	455,032,030	0.0	130.3	2.9	45.7	22.0	80.2
Unknown	0	76	27,928	0.0	---	---	---	---	---

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1
Glimepiride										
Female	33,277	33,277	132,668	5,277,493	5,386,634	14,748	167	48	119	6,312
Male	36,725	36,725	159,913	6,456,965	6,565,133	17,974	92	23	69	4,693
Unknown	1	1	1	30	40	0	0	0	0	0
Glipizide/Metformin										
Female	76,513	76,513	302,661	16,737,684	16,656,597	45,603	606	181	425	46,862
Male	86,506	86,506	367,505	20,647,042	20,530,086	56,208	675	121	554	40,385
Unknown	2	2	5	150	176	0	0	0	0	0
Glyburide/Metformin										
Female	37,446	37,446	137,675	6,213,351	6,313,139	17,284	261	73	188	10,805
Male	39,143	39,143	156,813	7,254,142	7,366,920	20,170	215	61	154	9,388
Unknown	4	4	5	150	138	0	0	0	0	0
Tolazamide										
Female	1,710	1,710	4,481	399,636	390,553	1,069	10	8	2	5,349
Male	1,929	1,929	5,202	468,568	459,445	1,258	17	10	7	2,937
Unknown	0	0	0	0	0	0	0	0	0	0
Pioglitazone/Metformin										
Female	25,731	25,731	99,837	4,054,486	4,169,415	11,415	31	5	26	172
Male	29,798	29,798	131,684	5,394,113	5,491,607	15,035	48	9	39	970
Unknown	2	2	2	130	105	0	0	0	0	0
Rosiglitazone/Metformin										
Female	6,809	6,809	27,233	947,437	982,319	2,689	9	5	4	302
Male	6,490	6,490	26,877	974,339	999,128	2,735	14	2	12	42
Unknown	0	0	0	0	0	0	0	0	0	0

Table 3: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Sex

	Time to Event Group 2	Eligible Members	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings / User	Days Supplied/ Dispensing	Total Events/ 100K Days at Risk	Total Events/1K Years at Risk
Glimepiride									
Female	14,842	1,254,280	565,663,333	26.5	158.6	4.0	39.8	3.1	11.3
Male	8,380	992,981	453,794,548	37.0	175.8	4.4	40.4	1.4	5.1
Unknown	0	76	27,958	13.2	30.0	1.0	30.0	0.0	0.0
Glipizide/Metformin									
Female	136,078	1,255,032	562,097,198	61.0	218.8	4.0	55.3	3.6	13.3
Male	211,110	993,609	450,613,244	87.1	238.7	4.2	56.2	3.3	12.0
Unknown	0	76	27,756	26.3	75.0	2.5	30.0	0.0	0.0
Glyburide/Metformin									
Female	27,196	1,254,786	564,218,074	29.8	165.9	3.7	45.1	4.1	15.1
Male	23,827	993,300	452,745,249	39.4	185.3	4.0	46.3	2.9	10.7
Unknown	0	76	27,738	52.6	37.5	1.3	30.0	0.0	0.0
Tolazamide									
Female	109	1,253,825	567,017,553	1.4	233.7	2.6	89.2	2.6	9.4
Male	5,859	992,347	454,852,266	1.9	242.9	2.7	90.1	3.7	13.5
Unknown	0	76	27,928	0.0	---	---	---	---	---
Pioglitazone/Metformin									
Female	4,017	1,255,423	565,094,256	20.5	157.6	3.9	40.6	0.7	2.7
Male	12,539	994,227	453,365,262	30.0	181.0	4.4	41.0	0.9	3.2
Unknown	0	76	27,928	26.3	65.0	1.0	65.0	0.0	0.0
Rosiglitazone/Metformin									
Female	144	1,254,146	566,391,267	5.4	139.1	4.0	34.8	0.9	3.3
Male	678	992,723	454,546,323	6.5	150.1	4.1	36.3	1.4	5.1
Unknown	0	76	27,938	0.0	---	---	---	---	---

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2	Eligible Members
Insulin (Rapid-Acting)												
2004	683	683	1,030	28,955	32,614	89	6	4	2	104	24	97,816
2005	756	756	1,099	33,003	36,333	99	6	3	3	100	318	115,314
2006	1,036	1,036	1,654	52,389	56,314	154	5	2	3	41	77	245,668
2007	1,488	1,488	2,074	66,929	72,964	200	9	4	5	129	1,135	359,575
2008	2,942	2,942	4,328	141,420	153,646	421	13	5	8	155	78	698,864
2009	3,906	3,906	5,690	188,278	202,357	554	20	3	17	36	966	816,503
2010	3,763	3,763	5,257	175,391	190,331	521	15	3	12	126	473	851,125
2011	4,014	4,014	5,727	198,303	212,016	580	35	7	28	151	1,037	880,348
2012	4,310	4,310	5,559	198,119	204,946	561	25	4	21	170	479	913,044
Insulin (Short-Acting)												
2004	0	0	0	0	0	0	0	0	0	0	0	97,764
2005	0	0	0	0	0	0	0	0	0	0	0	115,460
2006	0	0	0	0	0	0	0	0	0	0	0	245,878
2007	0	0	0	0	0	0	0	0	0	0	0	359,941
2008	0	0	0	0	0	0	0	0	0	0	0	699,421
2009	0	0	0	0	0	0	0	0	0	0	0	817,438
2010	0	0	0	0	0	0	0	0	0	0	0	852,436
2011	0	0	0	0	0	0	0	0	0	0	0	881,992
2012	0	0	0	0	0	0	0	0	0	0	0	914,911
Insulin (Long-Acting)												
2004	359	359	685	19,678	20,960	57	3	2	1	16	7	97,779
2005	404	404	928	31,018	32,862	90	2	2	0	13	0	115,455
2006	844	844	1,612	58,889	61,543	168	5	2	3	28	236	245,867
2007	1,659	1,659	2,805	97,012	103,068	282	10	2	8	95	267	359,853
2008	4,263	4,263	7,389	258,379	279,524	765	14	1	13	24	198	699,234
2009	6,254	6,254	10,490	386,047	409,895	1,122	20	2	18	55	2,219	816,869
2010	6,382	6,382	10,714	406,195	425,355	1,165	24	6	18	577	620	851,300
2011	7,093	7,093	11,228	443,131	464,097	1,271	33	6	27	428	649	880,526
2012	7,952	7,952	10,927	446,120	453,416	1,241	31	6	25	345	1,096	912,974

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Insulin (Rapid-Acting)							
2004	20,469,773	7.0	42.4	1.5	28.1	18.4	67.2
2005	25,191,285	6.6	43.7	1.5	30.0	16.5	60.3
2006	42,503,054	4.2	50.6	1.6	31.7	8.9	32.4
2007	66,212,440	4.1	45.0	1.4	32.3	12.3	45.1
2008	127,984,849	4.2	48.1	1.5	32.7	8.5	30.9
2009	170,417,481	4.8	48.2	1.5	33.1	9.9	36.1
2010	180,125,414	4.4	46.6	1.4	33.4	7.9	28.8
2011	190,064,530	4.6	49.4	1.4	34.6	16.5	60.3
2012	197,704,369	4.7	46.0	1.3	35.6	12.2	44.6
Insulin (Short-Acting)							
2004	20,469,101	0.0	---	---	---	---	---
2005	25,219,298	0.0	---	---	---	---	---
2006	42,550,762	0.0	---	---	---	---	---
2007	66,288,205	0.0	---	---	---	---	---
2008	128,109,456	0.0	---	---	---	---	---
2009	170,622,144	0.0	---	---	---	---	---
2010	180,429,410	0.0	---	---	---	---	---
2011	190,444,011	0.0	---	---	---	---	---
2012	198,129,885	0.0	---	---	---	---	---
Insulin (Long-Acting)							
2004	20,470,476	3.7	54.8	1.9	28.7	14.3	52.3
2005	25,216,701	3.5	76.8	2.3	33.4	6.1	22.2
2006	42,543,656	3.4	69.8	1.9	36.5	8.1	29.7
2007	66,269,234	4.6	58.5	1.7	34.6	9.7	35.4
2008	128,056,587	6.1	60.6	1.7	35.0	5.0	18.3
2009	170,503,869	7.7	61.7	1.7	36.8	4.9	17.8
2010	180,206,792	7.5	63.6	1.7	37.9	5.6	20.6
2011	190,149,088	8.1	62.5	1.6	39.5	7.1	26.0
2012	197,745,356	8.7	56.1	1.4	40.8	6.8	25.0

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2	Eligible Members
Insulin (Intermediate-Acting)												
2004	708	708	1,316	51,679	53,876	148	2	1	1	23	23	97,841
2005	704	704	1,717	71,032	73,393	201	4	1	3	24	393	115,371
2006	1,033	1,033	2,515	95,829	100,240	274	5	3	2	56	11	245,697
2007	1,277	1,277	3,309	135,040	140,366	384	9	4	5	218	172	359,591
2008	1,790	1,790	3,798	142,364	150,195	411	5	3	2	95	169	698,974
2009	2,132	2,132	4,315	169,360	175,353	480	10	2	8	158	392	816,735
2010	1,953	1,953	3,453	135,768	141,065	386	8	1	7	15	302	851,512
2011	2,189	2,189	4,106	160,602	166,634	456	17	5	12	170	436	880,771
2012	2,257	2,257	3,366	137,828	139,334	381	21	2	19	81	570	913,555
Insulin (Intermediate/Rapid-												
2004	219	219	471	18,879	19,488	53	4	1	3	26	305	97,773
2005	190	190	537	20,107	19,578	54	3	2	1	104	407	115,458
2006	246	246	657	26,495	27,403	75	4	1	3	31	2,789	245,864
2007	266	266	637	25,359	27,120	74	1	0	1	0	38	359,890
2008	400	400	918	37,581	39,541	108	3	1	2	1,207	6	699,338
2009	465	465	1,181	44,090	45,628	125	3	1	2	1,270	157	817,335
2010	419	419	860	35,448	37,341	102	3	1	2	60	894	852,284
2011	343	343	603	26,055	27,662	76	4	0	4	0	80	881,802
2012	338	338	513	21,800	22,679	62	4	1	3	42	31	914,703
Insulin (Intermediate/Short-												
2004	0	0	0	0	0	0	0	0	0	0	0	97,764
2005	0	0	0	0	0	0	0	0	0	0	0	115,460
2006	0	0	0	0	0	0	0	0	0	0	0	245,878
2007	0	0	0	0	0	0	0	0	0	0	0	359,941
2008	0	0	0	0	0	0	0	0	0	0	0	699,421
2009	0	0	0	0	0	0	0	0	0	0	0	817,438
2010	0	0	0	0	0	0	0	0	0	0	0	852,436
2011	0	0	0	0	0	0	0	0	0	0	0	881,992
2012	0	0	0	0	0	0	0	0	0	0	0	914,911

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Insulin (Intermediate-Acting)							
2004	20,476,887	7.2	73.0	1.9	39.3	3.7	13.6
2005	25,207,514	6.1	100.9	2.4	41.4	5.5	19.9
2006	42,513,434	4.2	92.8	2.4	38.1	5.0	18.2
2007	66,225,129	3.6	105.7	2.6	40.8	6.4	23.4
2008	128,018,386	2.6	79.5	2.1	37.5	3.3	12.2
2009	170,491,929	2.6	79.4	2.0	39.2	5.7	20.8
2010	180,244,863	2.3	69.5	1.8	39.3	5.7	20.7
2011	190,210,249	2.5	73.4	1.9	39.1	10.2	37.3
2012	197,856,450	2.5	61.1	1.5	40.9	15.1	55.0
Insulin (Intermediate/Rapid-							
2004	20,468,922	2.2	86.2	2.2	40.1	20.5	75.0
2005	25,218,457	1.6	105.8	2.8	37.4	15.3	56.0
2006	42,547,201	1.0	107.7	2.7	40.3	14.6	53.3
2007	66,280,275	0.7	95.3	2.4	39.8	3.7	13.5
2008	128,096,448	0.6	94.0	2.3	40.9	7.6	27.7
2009	170,604,819	0.6	94.8	2.5	37.3	6.6	24.0
2010	180,403,135	0.5	84.6	2.1	41.2	8.0	29.3
2011	190,411,154	0.4	76.0	1.8	43.2	14.5	52.8
2012	198,091,366	0.4	64.5	1.5	42.5	17.6	64.4
Insulin (Intermediate/Short-							
2004	20,469,101	0.0	---	---	---	---	---
2005	25,219,298	0.0	---	---	---	---	---
2006	42,550,762	0.0	---	---	---	---	---
2007	66,288,205	0.0	---	---	---	---	---
2008	128,109,456	0.0	---	---	---	---	---
2009	170,622,144	0.0	---	---	---	---	---
2010	180,429,410	0.0	---	---	---	---	---
2011	190,444,011	0.0	---	---	---	---	---
2012	198,129,885	0.0	---	---	---	---	---

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2	Eligible Members
Chlorpropamide												
2004	6	6	22	1,110	1,140	3	1	0	1	0	66	97,764
2005	5	5	12	500	537	1	0	0	0	0	0	115,458
2006	5	5	5	310	316	1	0	0	0	0	0	245,876
2007	5	5	11	330	351	1	0	0	0	0	0	359,941
2008	3	3	4	240	270	1	0	0	0	0	0	699,418
2009	7	7	20	720	812	2	0	0	0	0	0	817,434
2010	11	11	36	2,320	2,334	6	0	0	0	0	0	852,435
2011	3	3	12	360	373	1	0	0	0	0	0	881,985
2012	3	3	3	90	74	0	0	0	0	0	0	914,906
Glimepiride												
2004	655	655	3,432	113,170	116,145	318	5	0	5	0	311	97,791
2005	471	471	1,899	76,209	77,830	213	1	1	0	318	0	115,388
2006	1,533	1,533	8,289	331,158	336,031	920	4	3	1	91	190	245,843
2007	3,410	3,410	17,767	677,050	692,977	1,897	18	7	11	2,075	1,135	359,785
2008	8,870	8,870	44,306	1,719,624	1,760,196	4,819	34	6	28	1,353	5,552	698,902
2009	13,328	13,328	63,092	2,522,229	2,580,416	7,065	55	16	39	2,903	6,021	815,891
2010	13,886	13,886	63,004	2,529,567	2,581,057	7,067	56	19	37	2,293	4,088	849,365
2011	13,710	13,710	54,471	2,274,142	2,315,170	6,339	41	10	31	1,518	3,931	877,793
2012	14,140	14,140	36,322	1,491,339	1,491,985	4,085	45	9	36	454	1,994	909,751
Glipizide/Glipizide-Metformin												
2004	3,209	3,209	19,462	1,103,553	1,101,395	3,015	27	8	19	7,060	12,081	97,828
2005	4,590	4,590	26,323	1,590,839	1,578,699	4,322	40	17	23	9,522	25,372	115,104
2006	9,444	9,444	50,201	3,195,156	3,176,551	8,697	62	17	45	7,685	37,703	245,085
2007	16,041	16,041	80,297	5,191,020	5,165,549	14,143	131	44	87	18,064	74,572	358,123
2008	21,952	21,952	106,220	5,664,903	5,691,881	15,584	158	56	102	16,030	56,930	695,323
2009	26,899	26,899	122,569	6,413,529	6,436,670	17,623	214	52	162	13,319	55,445	810,819
2010	26,725	26,725	110,789	5,835,439	5,845,502	16,004	230	41	189	9,801	44,173	842,931
2011	27,415	27,415	94,496	5,189,093	5,166,931	14,146	244	46	198	4,470	28,791	870,016
2012	26,746	26,746	59,814	3,201,344	3,023,681	8,278	175	21	154	1,296	12,121	900,462

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Chlorpropamide							
2004	20,468,966	0.1	185.0	3.7	50.5	87.7	320.4
2005	25,219,023	0.0	100.0	2.4	41.7	0.0	0.0
2006	42,550,464	0.0	62.0	1.0	62.0	0.0	0.0
2007	66,287,904	0.0	66.0	2.2	30.0	0.0	0.0
2008	128,108,637	0.0	80.0	1.3	60.0	0.0	0.0
2009	170,621,061	0.0	102.9	2.9	36.0	0.0	0.0
2010	180,428,738	0.0	210.9	3.3	64.4	0.0	0.0
2011	190,442,645	0.0	120.0	4.0	30.0	0.0	0.0
2012	198,128,554	0.0	30.0	1.0	30.0	0.0	0.0
Glimepiride							
2004	20,471,150	6.7	172.8	5.2	33.0	4.3	15.7
2005	25,209,903	4.1	161.8	4.0	40.1	1.3	4.7
2006	42,540,258	6.2	216.0	5.4	40.0	1.2	4.3
2007	66,253,867	9.5	198.5	5.2	38.1	2.6	9.5
2008	128,003,095	12.7	193.9	5.0	38.8	1.9	7.1
2009	170,339,251	16.3	189.2	4.7	40.0	2.1	7.8
2010	179,867,114	16.3	182.2	4.5	40.1	2.2	7.9
2011	189,653,909	15.6	165.9	4.0	41.7	1.8	6.5
2012	197,147,292	15.5	105.5	2.6	41.1	3.0	11.0
Glipizide/Glipizide-Metformin							
2004	20,471,371	32.8	343.9	6.1	56.7	2.5	9.0
2005	25,158,442	39.9	346.6	5.7	60.4	2.5	9.3
2006	42,398,372	38.5	338.3	5.3	63.6	2.0	7.1
2007	65,961,821	44.8	323.6	5.0	64.6	2.5	9.3
2008	127,339,372	31.6	258.1	4.8	53.3	2.8	10.1
2009	169,370,153	33.2	238.4	4.6	52.3	3.3	12.1
2010	178,632,728	31.7	218.4	4.1	52.7	3.9	14.4
2011	188,105,479	31.5	189.3	3.4	54.9	4.7	17.2
2012	195,300,460	29.7	119.7	2.2	53.5	5.8	21.1

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2	Eligible Members
Glyburide/Glyburide-Metformin												
2004	5,190	5,190	21,352	1,268,297	1,267,826	3,471	32	9	23	2,236	3,301	97,959
2005	5,905	5,905	22,228	1,392,785	1,394,751	3,819	47	19	28	3,974	6,821	114,752
2006	6,264	6,264	24,379	1,339,385	1,344,138	3,680	43	16	27	3,145	4,373	244,424
2007	6,310	6,310	27,877	1,260,552	1,282,606	3,512	39	17	22	1,792	8,315	357,851
2008	9,771	9,771	43,324	1,797,278	1,843,417	5,047	46	16	30	2,734	5,250	696,669
2009	12,560	12,560	52,953	2,189,873	2,248,656	6,156	76	14	62	2,607	8,199	813,805
2010	11,407	11,407	45,603	1,870,581	1,918,830	5,253	72	18	54	2,043	6,951	847,563
2011	10,232	10,232	35,854	1,488,210	1,518,482	4,157	69	15	54	915	5,975	876,561
2012	8,954	8,954	20,923	860,682	861,491	2,359	52	10	42	747	1,838	908,924
Tolazamide												
2004	1,292	1,292	3,744	337,656	332,524	910	9	7	2	4,050	2,120	97,842
2005	1,176	1,176	3,305	294,696	289,605	793	9	7	2	2,978	350	115,315
2006	748	748	1,803	165,023	158,533	434	6	4	2	1,258	1,264	245,559
2007	170	170	401	35,660	34,750	95	1	0	1	0	1,399	359,622
2008	99	99	178	15,281	15,506	42	0	0	0	0	0	699,161
2009	50	50	88	7,068	6,912	19	0	0	0	0	0	817,188
2010	42	42	73	6,215	6,241	17	1	0	1	0	593	852,232
2011	23	23	39	3,455	3,353	9	0	0	0	0	0	881,760
2012	39	39	52	3,150	2,574	7	1	0	1	0	242	914,705
Pioglitazone/Pioglitazone-												
2004	1,412	1,412	7,822	338,868	342,469	938	1	1	0	37	0	97,915
2005	1,775	1,775	8,147	412,213	413,117	1,131	5	0	5	0	2,357	115,426
2006	4,368	4,368	23,018	1,059,962	1,069,008	2,927	5	0	5	0	4,604	245,744
2007	5,759	5,759	29,636	1,261,384	1,284,253	3,516	9	4	5	181	1,690	359,385
2008	10,129	10,129	45,141	1,772,777	1,822,156	4,989	16	4	12	456	3,155	698,115
2009	12,747	12,747	53,313	2,082,732	2,141,927	5,864	12	2	10	405	1,405	815,093
2010	10,616	10,616	39,817	1,550,448	1,594,276	4,365	22	2	20	41	2,769	848,816
2011	5,971	5,971	18,456	726,919	750,347	2,054	8	1	7	22	575	877,388
2012	2,754	2,754	6,173	243,426	243,574	667	1	0	1	0	1	909,685

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Glyburide/Glyburide-Metformin							
2004	20,478,464	53.0	244.4	4.1	59.4	2.5	9.2
2005	25,098,657	51.5	235.9	3.8	62.7	3.4	12.3
2006	42,284,606	25.6	213.8	3.9	54.9	3.2	11.7
2007	65,902,699	17.6	199.8	4.4	45.2	3.0	11.1
2008	127,582,108	14.0	183.9	4.4	41.5	2.5	9.1
2009	169,902,938	15.4	174.4	4.2	41.4	3.4	12.3
2010	179,473,474	13.5	164.0	4.0	41.0	3.8	13.7
2011	189,356,019	11.7	145.4	3.5	41.5	4.5	16.6
2012	196,912,096	9.9	96.1	2.3	41.1	6.0	22.0
Tolazamide							
2004	20,475,800	13.2	261.3	2.9	90.2	2.7	9.9
2005	25,192,983	10.2	250.6	2.8	89.2	3.1	11.4
2006	42,496,719	3.0	220.6	2.4	91.5	3.8	13.8
2007	66,232,365	0.5	209.8	2.4	88.9	2.9	10.5
2008	128,062,094	0.1	154.4	1.8	85.8	0.0	0.0
2009	170,574,480	0.1	141.4	1.8	80.3	0.0	0.0
2010	180,383,146	0.0	148.0	1.7	85.1	16.0	58.5
2011	190,396,110	0.0	150.2	1.7	88.6	0.0	0.0
2012	198,084,050	0.0	80.8	1.3	60.6	38.9	141.9
Pioglitazone/Pioglitazone-							
2004	20,482,282	14.4	---	---	---	---	---
2005	25,205,185	15.4	232.2	4.6	50.6	1.2	4.4
2006	42,509,910	17.8	242.7	5.3	46.0	0.5	1.7
2007	66,176,699	16.0	219.0	5.1	42.6	0.7	2.6
2008	127,830,819	14.5	175.0	4.5	39.3	0.9	3.2
2009	170,143,434	15.6	163.4	4.2	39.1	0.6	2.0
2010	179,673,866	12.5	146.0	3.8	38.9	1.4	5.0
2011	189,473,707	6.8	121.7	3.1	39.4	1.1	3.9
2012	196,991,544	3.0	88.4	2.2	39.4	0.4	1.5

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	New Users	New Episodes	Dispensings	Total Days Supplied	Days at Risk	Years at Risk	New Events - Total	New Events - Group 1	New Events - Group 2	Time to Event Group 1	Time to Event Group 2	Eligible Members
Rosiglitazone/Rosiglitazone-												
2004	1,961	1,961	11,668	366,794	376,961	1,032	7	2	5	21	222	97,817
2005	1,297	1,297	5,467	181,851	187,855	514	3	1	2	38	52	115,289
2006	2,554	2,554	11,445	440,652	448,449	1,228	0	0	0	0	0	245,699
2007	2,416	2,416	9,320	344,812	354,407	970	2	0	2	0	162	359,497
2008	1,958	1,958	7,010	250,064	260,322	713	3	2	1	250	69	698,458
2009	2,134	2,134	6,701	245,816	256,789	703	7	2	5	35	312	816,443
2010	896	896	2,345	85,525	89,814	246	1	0	1	0	5	851,299
2011	83	83	154	6,262	6,850	19	0	0	0	0	0	880,908
2012	0	0	0	0	0	0	0	0	0	0	0	913,992

Table 4: Summary of Incident ADA Use and Events in the MSDD between January 1, 2004 and December 31, 2012, by ADA Product and Year

	Member-Days	New Users/ 1K Eligible Members	Days Supplied/ User	Dispensings/ User	Days Supplied/ Dispensing	Total Events/100K Days at Risk	Total Events/1K Years at Risk
Rosiglitazone/Rosiglitazone-							
2004	20,472,902	20.0	187.0	6.0	31.4	1.9	6.8
2005	25,189,130	11.2	140.2	4.2	33.3	1.6	5.8
2006	42,511,168	10.4	172.5	4.5	38.5	0.0	0.0
2007	66,196,031	6.7	142.7	3.9	37.0	0.6	2.1
2008	127,891,219	2.8	127.7	3.6	35.7	1.2	4.2
2009	170,402,635	2.6	115.2	3.1	36.7	2.7	10.0
2010	180,191,397	1.1	95.5	2.6	36.5	1.1	4.1
2011	190,194,533	0.1	75.4	1.9	40.7	0.0	0.0
2012	197,916,513	0.0	---	---	---	---	---